UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EMELY MONTERO,	:	
	:	
Plaintiff,	:	**ORDER GRANTING MOTION FOR JUDGMENT ON THE PLEADINGS**
	:	
-against-	:	
	:	
TEVA PHARMACEUTICALS USA INC., and ORTHO MCNEIL JANSSEN PHARMACEUTICALS, INC.,	:	19 Civ. 9304 (AKH)
	:	
Defendants.	:	

ALVIN K. HELLERSTEIN, U.S.D.J.:

Plaintiff Emely Montero brings various state law claims to recover for alleged injuries stemming from her use of an oral contraceptive. Defendant Teva Pharmaceuticals USA Inc. ("Teva"), the manufacturer of the oral contraceptive, moves for judgment on the pleadings. Because all of Plaintiff's claims are preempted by federal law and/or insufficiently pleaded, Teva's motion is granted.

BACKGROUND[1]

Teva, the world's leading generic pharmaceutical company, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the oral contraceptive Tri-Lo Sprintec. Tri-Lo Sprintec is the generic version of Ortho Tri-Cyclen Lo. Ortho Tri-Cyclen Lo is produced by Ortho McNeil Janssen Pharmaceuticals, Inc. ("Janssen," and together with Teva, "Defendants"), who was previously dismissed as a defendant in this case. *See* ECF No. 27.

[1] Facts are taken from the Complaint, ECF No. 1-1. I accept all factual allegations in the Complaint as true for purposes of this motion. *Hayden v. Paterson*, 594 F.3d 150, 160 (2d Cir. 2010).

Montero took Tri-Lo Sprintec, Teva's generic product, from approximately February 2010 until August 2016. Tri-Lo Sprintec allegedly caused Montero to suffer from life-threatening blood clots, resulting once in a pulmonary embolism, among other injuries. Montero alleges that even though Defendants[2] promoted Tri-Lo Sprintec as safe and effective, the medication actually carried life-threatening risks, including the risk of serious blood clots. Defendants allegedly failed to perform sufficient tests of Tri-Lo Sprintec before introducing it to the market. Furthermore, Defendants allegedly failed to provide adequate warnings to the Food and Drug Administration ("FDA"), the medical community, and consumers about the product's risks.

Montero brought this suit against Teva and Janssen for negligence, strict products liability, breach of express warranty, breach of implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud. On December 4, 2019, I dismissed all claims against Janssen because Janssen does not manufacture, distribute, or sell Tri-Lo Sprintec. Janssen is not responsible for injuries arising from the generic version of its product. *See Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 721-22 (S.D.N.Y. 2017) ("New York authorities are consistent with the majority of other courts around the country in rejecting liability for a company that itself did not manufacture, sell, or distribute generic versions of its name-brand drug."). Teva, the only remaining defendant, now moves for judgment on the pleadings. Teva argues Montero's claims are preempted by federal law and are insufficiently pleaded.

[2] Even though Plaintiff concedes that Janssen produces Ortho Tri-Cyclen Lo, not Tri-Lo Sprintec, the Complaint repeatedly uses the plural "Defendants" in discussing the design, research, manufacture, testing, advertisement, promotion, marketing, sale, and distribution of Tri-Lo Sprintec. Though this is likely the result of poor drafting, I use the plural "Defendants" consistently with the allegations in the Complaint. In granting Janssen's motion to dismiss, I took judicial notice of FDA records indicating that Janssen does not produce Tri-Lo Sprintec.

DISCUSSION

I. Legal Standard

The standard on a 12(c) motion is the same as that on a 12(b)(6) motion. *Hayden v. Paterson*, 594 F.3d 150, 160 (2d Cir. 2010). Thus, I "will accept all factual allegations in the complaint as true and draw all reasonable inferences in [Plaintiff's] favor. To survive a Rule 12(c) motion, [Plaintiff's] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Id.* (internal quotation marks omitted).

II. Preemption by Federal Law

Under the Constitution's Supremacy Clause, federal law "shall be the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, "state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Federal law preempts state law "where it is impossible for a private party to comply with both state and federal law." *Id.*

Following the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments, brand-name and generic drug manufacturers have different obligations with respect to drug labeling. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011). While "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," "[a] manufacturer seeking generic drug approval is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 613 (citing, *e.g.*, 21 U.S.C. § 355(b)(1), (d), (j)(2)(A)(v), (j)(4)(G)). The FDA interprets its regulations to mean that generic drugs must continue to match the brand name's labeling after FDA approval. *Id.* Thus, labeling for a generic drug must be identical to the labeling of the

corresponding brand-name drug; generic drug manufacturers cannot independently make changes to their drugs' labels, even to strengthen warnings. *Id.* at 613-17. In *Mensing*, the Supreme Court held that federal laws imposing this requirement conflict with, and thus preempt, state law claims alleging that a generic drug should have included stronger warning labels. 564 U.S. at 618-19.

Mensing only addressed failure-to-warn claims. In *Mutual Pharmaceutical Co., Inc. v. Bartlett*, the Supreme Court reiterated the holding in *Mensing* and extended the same principle to a design-defect claim against a generic drug manufacturer. The Court held that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under [*Mensing*]." 570 U.S. 472, 476 (2013). Under the state design-defect law at issue in *Bartlett*, a drug manufacturer could avoid liability by either redesigning its drug or strengthening its warning label. However, federal law prohibits a generic drug manufacturer from doing either. The manufacturer cannot change a generic drug's composition or its label. *Id.* at 483-84.

Montero's allegations generally fall into three categories: 1) defective design (*i.e.*, that Tri-Lo Sprintec is unsafe), 2) inadequate testing (*i.e.*, that Defendants failed to perform sufficient testing to understand the risks of Tri-Lo Sprintec), and 3) failure to warn[3] (*i.e.*, that Defendants failed to disclose adequately the risks of Tri-Lo Sprintec). Claims proceeding under any of these theories are preempted.

As to design, *Bartlett* defeats any claim premised on the theory that Teva should have designed a safer product. *See* 570 U.S. at 483-84 (finding it would be impossible to redesign generic drug while complying with federal law); *see also Coleson v. Qualitest Pharm.*

[3] Plaintiff's fraud-based at least nominally go beyond failure to warn. As discussed at Point III, *infra*, these claims are insufficiently pleaded.

Manufacture, No. 17-CV-5381, 2018 WL 2108238, at *3 (S.D.N.Y. May 7, 2018) (holding claims related to design defect were preempted because generic drug manufacturer could not "fiddle with [drug's] composition to mitigate . . . possible side effect, without violating federal law").

Plaintiff's theory regarding inadequate testing fails for similar reasons. Plaintiff suggests that with further testing, perhaps Teva would have concluded that Tri-Lo Sprintec was too dangerous for the market. Under *Bartlett*, this theory also does not save a claim from preemption. *See Bartlett*, 570 U.S. at 488 (rejecting "'stop-selling' rationale as incompatible with . . . pre-emption jurisprudence" because "pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability"); *see also Beswick v. Sun Pharm. Indus., Ltd.*, No. 10-CV-00357A(F), 2018 WL 704399, at *7 (W.D.N.Y. Jan. 30, 2018) ("Insofar as [claims] can be construed as alleging Defendant should have . . . pulled the products from the market, in *Bartlett*, the Supreme Court has held such actions incompatible with *Mensing*.").

Finally, any claims premised on failure to warn are preempted. *See Mensing*, 564 U.S. at 608-09, 618-19 (concluding federal law preempts "state tort-law claims based on . . . drug manufacturers' alleged failure to provide adequate warning labels for generic" drug). Plaintiff alleges inadequate warnings not only in Tri-Lo Sprintec's packaging but also in Defendants' communications with healthcare providers and advertisements to the public. The preemption of failure-to-warn claims extends to these latter types of communications as well. *See In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 419 (S.D.N.Y. 2013) ("[A]ny claims stemming from the [generic drug manufacturers'] alleged failure to communicate additional warnings through some method other than their package inserts are preempted.").

Plaintiff does not make any arguments to the contrary. Plaintiff's opposition does not address *Mensing*, *Bartlett*, or their progeny. Instead, it relies exclusively on case law that is inapposite and/or predates *Mensing*. A court in this district explained succinctly when dismissing claims against two manufacturers of a generic drug that allegedly caused injury:

> [T]he defendants could not have altered [the drug]'s label to strengthen its warnings about [the side effect], nor fiddle with its composition to mitigate that possible side effect, without violating federal law. However, just as with the claims at issue in *Mensing* and *Bartlett*, the plaintiff's failure to warn and design defect claims in this action would have required the defendants to do just that. Thus, just as in those cases, the plaintiff's claims are preempted.

Coleson v. Qualitest Pharm. Manufacture, No. 17-CV-5381, 2018 WL 2108238, at *3 (S.D.N.Y. May 7, 2018).

It is true that the preemption doctrine leaves Plaintiff with little recourse against the manufacturer whose drug allegedly injured her. *See Bartlett*, 570 U.S. at 520 (Sotomayor, J., dissenting) (noting decision "has left a seriously injured consumer without any remedy"). *Bartlett* recognized that consequence but left the issue to Congress. *See* 570 U.S. at 492-93.

III. Insufficient Pleading of Fraud

The Complaint includes claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud. *Mensing*, in addressing preemption of claims for failure to warn, did not address claims for affirmative misrepresentation or concealment. Here, Plaintiff's claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud rely primarily on allegations regarding the labeling of Tri-Lo Sprintec. Fraud-based claims are still preempted to the extent they are tied to labeling. *Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 189 (E.D.N.Y. 2012). *Mensing* makes clear that it would have been impossible for Teva to change Tri-Lo Sprintec's label and remain in compliance with federal law. *See* 564 U.S. at 618.

To the extent Plaintiff's fraud-based claims go beyond labeling, they are insufficiently pleaded. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Plaintiff's claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud are all subject to the heightened pleading standard of Rule 9(b). *See Pilkington N. Am., Inc. v. Mitsui Sumitomo Ins. Co. of Am.*, 420 F. Supp. 3d 123, 141-42 (S.D.N.Y. 2019) (holding negligent misrepresentation claim is subject to Rule 9(b) standard where it is not sufficiently distinct from claim alleging intentional misrepresentation based on the same facts); *Sterling Nat'l Bank & Tr. Co. of N.Y. v. Federated Dep't Stores, Inc.*, 612 F. Supp. 144, 147-48 (S.D.N.Y. 1985) (dismissing claims for fraudulent misrepresentation and fraudulent concealment due to failure to satisfy pleading requirements of Rule 9(b)).

Under Rule 9(b), for claims alleging misrepresentation, "plaintiff must plead the time, place and content of an alleged false representation." *Sterling Nat'l Bank*, 612 F. Supp. at 147. For claims alleging concealment or omission, a plaintiff must plead "(1) what the omissions were; (2) the person responsible for the failure to disclose; (3) the context of the omissions and the manner in which they misled the plaintiff; and (4) what the defendant obtained through fraud." *Soroof Trading Dev. Co., Ltd. v. GE Fuel Cell Sys., LLC*, 842 F. Supp. 2d 502, 513 (S.D.N.Y. 2012). Plaintiff does not do so. The Complaint alleges misrepresentation, omission, and concealment only in conclusory terms, failing to identify any particular misleading statement or act of concealment. These claims also do not differentiate between Defendants, much less identify a particular speaker or the person responsible for the failure to disclose. Plaintiff's brief does not include any facts that she could plead to elevate her claims above the required standard.

CONCLUSION

For the foregoing reasons, Teva's motion for judgment on the pleadings is granted, and the Complaint is dismissed with prejudice. The oral argument scheduled for May 12, 2020 is canceled. The Clerk is directed to terminate the open motion (ECF No. 28) and to close the case.

SO ORDERED.

Dated: New York, New York
April 14, 2020

/s/ Alvin K. Hellerstein
ALVIN K. HELLERSTEIN
United States District Judge